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FROM : Oleg F. Kaplun, Esq.
Fay Kaplun & Marcin, LLP

DATE : March 1, 2006

SUBJECT : U.S. Patent Appln. Serial No. 09/603,886
*for Apparatus and Method for Performing a Tissue
Resectioning Procedure*
Our Ref.: 10121/00901

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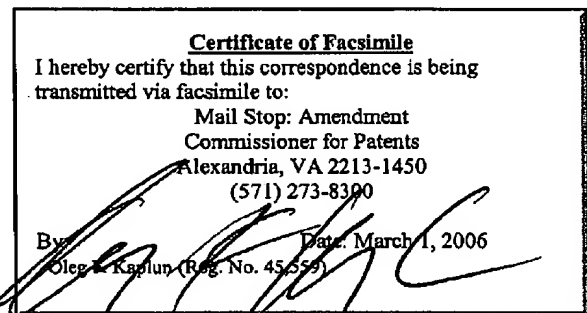
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[10121/00901]

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**RECEIVED
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Applicant(s) : Sullivan
Serial No. : 09/603,886
Filed : June 26, 2000
For : Apparatus and Method for Performing a Tissue Resection Procedure
Group Art Unit : 3737
Examiner : Ruth S. Smith

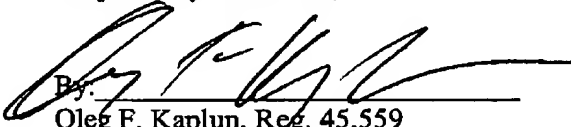
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**TRANSMITTAL**

Transmitted herewith please find a Reply Brief in response to the Examiner's Answer mailed on January 12, 2006 for filing in the above-identified application. No fees are believed to be required. The Commissioner is hereby authorized to charge any additional required fees to the Deposit Account of Fay Kaplun & Marcin, LLP No. 50-1492. A copy of this paper is enclosed for that purpose.

Respectfully submitted,

Dated: March 1, 2006


By: _____
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[10121/00901]

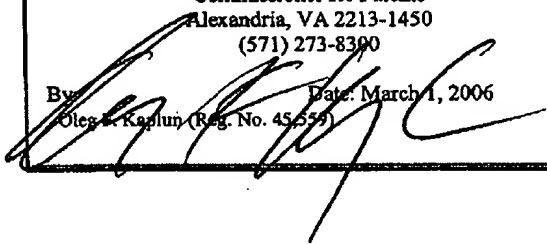
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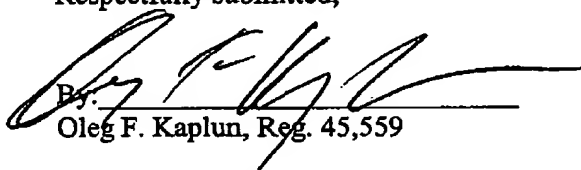
By:  Date: March 1, 2006
Oleg F. Kaplun (Reg. No. 45,559)

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REPLY BRIEF UNDER 37 C.F.R. § 41.41

In response to the Examiner's Answer mailed January 12, 2006 to the appellant's Appeal Brief filed October 11, 2005, and pursuant to 37 C.F.R. § 41.41, appellant presents this reply brief in the above-captioned application.

This is an appeal to the Board of Patent Appeals and Interferences from the Examiner's final rejection of claims 33 - 42 in the final Office Action dated March 31, 2005, clarified in the Advisory Action of June 9, 2005 and further clarified in the Examiner's Answer mailed January 12, 2006. The appealed claims are set forth in the attached Claims Appendix.

Serial No.: 09/603,886

Group Art Unit: 3737

Attorney Docket No.: 10121/00901

1. Grounds of Rejection to be Reviewed on Appeal

- I. Whether claims 33 - 36 and 40 are unpatentable under 35 U.S.C. § 103(a) as obvious over McGuckin, Jr. (U.S. Patent No. 5,868,760) in view of Murphy-Chutorian (U.S. Patent No. 5,891,133).
- II. Whether claim 37 is unpatentable under 35 U.S.C. § 103(a) as obvious over McGuckin, Jr. in view of Murphy-Chutorian in further view of Osterholm (U.S. Patent No. 4,830,849).
- III. Whether claims 38 - 39 are unpatentable under 35 U.S.C. § 103(a) as obvious over McGuckin, Jr. in view of Murphy-Chutorian in further view of Aida (U.S. Patent No. 5,485,839).
- IV. Whether claims 41 - 42 are unpatentable under 35 U.S.C. § 103(a) as obvious over McGuckin, Jr. in view of Murphy-Chutorian in further view of Kreizman et al. (U.S. Patent No. 6,214,018).

2. Argument

- I. The Rejection of Claims 33 - 36 and 40 Under 35 U.S.C. § 103(a) as Obvious Over McGuckin, Jr. in view of Murphy-Chutorian Should Be Reversed

In the Examiner's Answer, the Examiner states that McGuckin, Jr. teaches the invention substantially as claimed except for the use of a marker but that Murphy-Chutorian describes a catheter device having a marker.

Claim 33 recites a tissue resectioning system, comprising "a resection head mounted at a distal end of an elongate flexible body, *the resection head including a marker thereon* wherein, when in an operative position, the resection head is located within a body lumen with the elongate flexible body extending through the body lumen from a naturally occurring body orifice" and "an imager which remains outside the patient's body, the imager

Serial No.: 09/603,886
Group Art Unit: 3737
Attorney Docket No.: 10121/00901

generating image data of a selected region within the patient's body including *a predetermined portion of tissue marked for resection*" in combination with "an image processing unit analyzing the image data to define a region of tissue to be resectioned and to locate the marker" and "*a control unit controlling the resection head based on the defined region of tissue and the location of the marker to resect the region of tissue.*"

Initially, it is noted that neither McGuckin, Jr. nor Murphy-Chutorian describes either marking tissue or a control unit controlling resection of the marked tissue. The Examiner states that McGuckin, Jr. describes a tissue resectioning apparatus having an operating capsule 12 at the distal end of a flexible tubular member 16 and that the apparatus may be used with endoscopic or diagnostic imaging guidance. Even assuming the Examiner is correct, McGuckin Jr. teaches, at best, visualization of the operating capsule 12, but neither discloses nor suggests "*a predetermined portion of tissue marked for resection*" or "*a control unit controlling the resection head based on the defined region of tissue and the location of the marker to resect the region of tissue.*" That is, even if McGuckin, Jr. teaches allowing an operator to visualize the operating capsule 12, there is no *tissue* marked for resection (i.e., no tissue which could be distinguished as target tissue by such visualization means), and any guidance of the operating capsule 12 is manual. Thus, the operator must visually identify a region of tissue to resect and guide the operating capsule 12 based on this visual data. The operating capsule 12 provides no feedback indicating whether the tissue being resected is in fact the target tissue. In contrast, the present invention provides an imager generating image data corresponding to "*a predetermined portion*

Serial No.: 09/603,886
Group Art Unit: 3737
Attorney Docket No.: 10121/00901

of tissue marked for resection” and a control unit defines a region of tissue to be resected based on this data. The control unit identifies a location of the marker on the resection head to determine its position relative to the tissue to be resected, and controls resection of the defined region of tissue based on the location of the marker (and the resection head) relative to the defined region. It is respectfully submitted that McGuckin, Jr. neither discloses nor suggests marking tissue to be resected and, clearly neither shows nor suggests, using a control unit to control resection of thereof based on image data including a portion of tissue marked for resection.

Murphy-Chutorian is entirely unrelated to tissue resection. Rather, Murphy-Chutorian describes a catheter device for performing intra-coronary laser-assisted transmyocardial revascularization which includes a radio-opaque tip 154 for monitoring a position of the catheter device using a fluoroscope. *Murphy-Chutorian*, col. 11, lines 58-62. Murphy-Chutorian, like McGuckin, Jr., only teaches monitoring the position of the catheter device, and neither discloses nor suggests marking tissue for any purpose – much less for resection, or controlling the device based on the marked tissue and a location of the device relative thereto. Furthermore, it is respectfully submitted that the catheter device in Murphy-Chutorian is not inserted through a naturally occurring bodily orifice. *Id.* at Abstract. In fact, as the catheter device is for use within blood vessels, this would be impossible. Thus, it is respectfully submitted that Murphy-Chutorian fails to disclose or suggest marking tissue to define a region of tissue to be resected and using a control unit to control resection of the marked

Serial No.: 09/603,886
Group Art Unit: 3737
Attorney Docket No.: 10121/00901

tissue based on the location of the marker (and resection head) relative to the marked tissue.

Therefore, appellant respectfully submits that neither McGuckin, Jr. nor Murphy-Chutorian, either alone or in combination, discloses or suggests "a resection head mounted at a distal end of an elongate flexible body, *the resection head including a marker thereon* wherein, when in an operative position, the resection head is located within a body lumen with the elongate flexible body extending through the body lumen from a naturally occurring body orifice" and "an imager which remains outside the patient's body, the imager generating image data of a selected region within the patient's body including *a predetermined portion of tissue marked for resection*" in combination with "an image processing unit analyzing the image data to define a region of tissue to be resectioned and to locate the marker" and "*a control unit controlling the resection head based on the defined region of tissue and the location of the marker to resect the region of tissue,*" as recited in claim 33. Thus, it is respectfully requested that the Board reverse the rejection of claim 33 and the claims (34-36 and 40) which depend therefrom.

II. The Rejection of Claim 37 Under 35 U.S.C. § 103(a) as Obvious Over McGuckin, Jr. in view of Murphy-Chutorian in further view of Osterholm Should Be Reversed

Osterholm describes a system for circulating an oxygenated nutrient emulsion through a portion of the cerebrospinal pathway as a treatment for ischemic neurologic tissue. Appellant respectfully submits that Osterholm does not cure the above-described deficiencies of McGuckin,

Serial No.: 09/603,886
Group Art Unit: 3737
Attorney Docket No.: 10121/00901

Jr. and Murphy-Chutorian. Thus, because claim 37 depends from, and, therefore includes all of the limitations of claim 33, it is respectfully submitted that this claim is allowable for the reasons discussed above in regard to claim 33 and that the Board should reverse this rejection.

III. The Rejection of Claims 38 and 39 Under 35 U.S.C. § 103(a) as Obvious Over McGuckin, Jr. in view of Murphy-Chutorian in further view of Aida Should Be Reversed

Aida purports to show a tissue therapy system including an alarm means notifying an operating physician of deviation from a predetermined treatment plan. However, Aida et al. is directed to a non-surgical device -- an ultrasonic device for the treatment of calculi. Thus, it is respectfully submitted that Aida does not cure the above-described deficiencies of McGuckin, Jr. and Murphy-Chutorian and, in any case, none of the cited references provides any motivation for the combination suggested by the Examiner. Because claims 38 and 39 depend from, and, therefore include all of the limitations of claim 33, it is respectfully submitted that these claims are allowable for the same reasons discussed above in regard to claim 33 and the Board should reverse this rejection.

IV. The Rejection of Claims 41 and 42 Under 35 U.S.C. § 103(a) as Obvious Over McGuckin, Jr. in view of Murphy-Chutorian in further view of Kreizman et al. Should Be Reversed

Kreizman et al. shows a rigid device requiring a body part holder to immobilize a body part including tissue to be removed so that a point of reference may be defined relative to the immobilized body part. An operator defines a region of the tissue on an interactive display,

Serial No.: 09/603,886

Group Art Unit: 3737

Attorney Docket No.: 10121/00901

and the rigid device is inserted into the region to remove the tissue. Appellant respectfully submits that such a system is wholly unsuitable for use with a flexible device inserted via a naturally occurring body orifice as claimed and that, therefore, Kreizman does not cure the above-described deficiencies of McGuckin, Jr. and Murphy-Chutorian. That is, a flexible device inserted through a body lumen would not provide the reference point required by Kreizman. Furthermore, a position of the rigid device is determined based on a position of a guiding stage relative to the point of reference, not a marker included on a resection head, as recited in claim 33. Therefore, because claims 41 and 42 depend from, and, include all of the limitations of claim 33, it is respectfully submitted that these claims are allowable for the same reasons described above in regard to claim 33 and the Board should reverse this rejection.

Serial No.: 09/603,886

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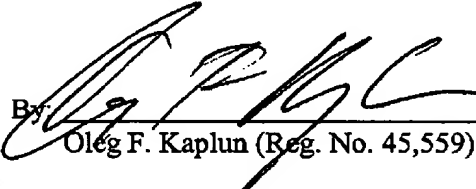
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3. Conclusions

For the reasons set forth above, Appellants respectfully request that the Board reverse the final rejections of the claims by the Examiner under 35 U.S.C. § 103(a), and indicate that claims 33 - 42 are allowable.

Respectfully submitted,

Date: March 1, 2006

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Serial No.: 09/603,886

Group Art Unit: 3737

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CLAIMS APPENDIX

33. A tissue resectioning system, comprising:

a resection head mounted at a distal end of an elongate flexible body, the resection head including a marker thereon wherein, when in an operative position, the resection head is located within a body lumen with the elongate flexible body extending through the body lumen to a naturally occurring body orifice;

an imager which remains outside the patient's body, the imager generating image data of a selected region within the patient's body including a predetermined portion of tissue marked for resection;

an image processing unit analyzing the image data to define a region of tissue to be resectioned and to locate the marker; and

a control unit controlling the resection head based on the defined region of tissue and the location of the marker to resect the region of tissue.

34. The system according to claim 33 wherein the imager includes a fluoroscope and an x-ray imaging sensor.

35. The system according to claim 33 wherein the marker is radiopaque.

Serial No.: 09/603,886

Group Art Unit: 3737

Attorney Docket No.: 10121/00901

36. The system according to claim 33 wherein the defined region of tissue and the location of the marker are displayed on a video display coupled with the control unit.

37. The system according to claim 33 wherein the control unit disables the resection head if the marker indicates that the resection head is oriented outside the defined region of tissue.

38. The system according to claim 33 further comprising an alarm device wherein the control unit transmits an alarm signal to the alarm device when the marker indicates that the resection head is oriented outside the defined region of tissue.

39. The system according to claim 38 wherein the alarm device generates a visual alarm.

40. The system according to claim 33 wherein the imager is a magnetic resonance imager.

41. The system according to claim 33 wherein the image processing unit determines the defined region of tissue by an absolute measure of tissue.

42. The system according to claim 33 wherein the image processing unit determines the defined region of tissue by a percentage of a physical dimension of the lesion.

Serial No.: 09/603,886

Group Art Unit: 3737

Attorney Docket No.: 10121/00901

EVIDENCE APPENDIX

No evidence has been entered or relied upon in the present appeal.

Serial No.: 09/603,886

Group Art Unit: 3737

Attorney Docket No.: 10121/00901

RELATED PROCEEDING APPENDIX

No decisions have been rendered regarding the present appeal or any proceedings related thereto.